K070193

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

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MAY - 2 2007

Contact Person: Mr. Klaus Huebner, Ph.D.

Position/Title: Manager of R & D

Date of Preparation: April 4, 2007

(2) **Trade Name:** EnviteC OxiPen Pulse Oximeter and Accessories

Common/Classification Name: OXIMETER

Product Code(s): DQA; 21 CFR §870.2700

Class: Class II

(3) **Predicate Device(s):** Substantial Equivalence to:

K Number	Model	Manufacturer
K963707	NBP 40 Handheld Pulse Oximeter	Nellcor Puritan Bennett (TYCO)

Reason for Submission: New device

(4) **Description of Device:**

The OxiPen Pulse Oximeter is a compact battery-powered handheld monitor designed for simplicity and portability for spot checking applications. It does not provide alarms or settable alarm limits.

The OxiPen features large readable numeric displays for SpO_2 and pulse rate and a pulse bar indicator for visual assessment of pulsation. Additional indicators include a signal quality LED and heart symbol which show pulsation, a sensor symbol for disconnection alert, and a battery capacity symbol.

Like the referenced predicate device, the OxiPen provides an audible pulse tone which varies with saturation level, as well as audible and visual alerts for conditions like sensor disconnect and power-off. The LCD display may be backlit by briefly pressing any key.

The OxiPen is provided with sensors specifically designed for use with the device, and features a compact connector with EnviteC proprietary pin-out.

(5) **Intended use:**

The measurement of functional oxygen saturation of arterial hemoglobin (SpO_2) has been a standard of care in the USA for 20 years. Applications for oximetry include monitoring in the anesthesia, recovery, and critical care environments, as well as transport monitoring and home care. The OxiPen device has no alarms or settable alarm limits and is intended for spot checking.

Indications for Use:

The EnviteC OxiPen Pulse Oximeter is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO_2), and pulse rate (measured by SpO_2 sensor accessories).

The monitor is intended for use on adult and pediatric patients in hospitals, hospital-type facilities, mobile, and home environments.

Prescription device.

(6) **Technological Characteristics:**

The EnviteC OxiPen Pulse Oximeter and accessory sensors employ the same technological characteristics as the predicate device and other oximeters to determine functional arterial oxygen saturation – arterially perfused tissue is illuminated sequentially by two wavelengths of light emitted by light emitting diodes (LED's), and the time varying absorbance of the tissue is measured from a photodiode light sensor. The resultant electrical signal is amplified, digitized, and analyzed to determine the functional oxygen saturation and pulse rate. The information is displayed on a liquid crystal display with pulse bar graph and audible pulse tone.

The OxiPen utilizes a two-layer architecture in which the oximeter-specific functions are managed by a dedicated subsystem (ChipOx) and the monitor functions including power management, display, and user interface are controlled separately.

(b) (1) **Non-Clinical Tests Submitted:**

The monitor and accessory sensors were tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, environmental operation and storage conditions, resistance to moisture ingress, and shock and vibration. The device passed all of the tests.

The monitor and accessory sensors were tested for pulse rate with a listed simulator. The device passed all of the tests.

Embedded software in the device was verified to requirements and validated to meet intended use by software and system level performance testing.

Sensor patient contact materials meet applicable standards for biocompatibility.

(2) **Clinical Tests Submitted:**

Clinical testing was performed to validate the performance and accuracy of the EnviteC OxiPen Pulse Oximeter and accessory sensors under controlled hypoxia versus arterial oxygen saturation as determined by co-oximetry. All testing was performed under an institutionally approved protocol with subject confidentiality and informed consent. Clinical test results support the stated accuracy claims for the specified range of 70% to 100% SaO_2.

(3) **Conclusions from Tests:**

As described in (b)(1) and (b)(2) above, the EnviteC OxiPen Pulse Oximeter and accessory sensors perform in a manner equivalent to the predicate device as substantiated by parameter, bench, and clinical testing. Device safety is substantiated by compliance testing to applicable standards and by biocompatibility of patient contact materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EnviteC-Wismar GmbH
C/O Mr. Stephen H. Gorski
Imagenix, Incorporated
S65 W35739 Piper Road
Eagle, Wisconsin 53119

MAY - 2 2007

Re: K070193
Trade/Device Name: EnviteC OxiPen® Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 6, 2007
Received: April 10, 2007

Dear Mr. Gorski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: EnviteC OxiPen® Pulse Oximeter

Indications for use:

The EnviteC OxiPen Pulse Oximeter is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO_2), and pulse rate (measured by SpO_2 sensor accessories).

The monitor is intended for use on adult and pediatric patients in hospitals, hospital-type facilities, mobile, and home environments.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Prescription Use ____X____ AND / OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] Sign-Off)
[illegible]sion of Anesthesiology, General Hospital,
[illegible]ection Control, Dental Devices

[illegible](k) Number: K070193